Environment

HPV vaccine deaths: Parliament panel indicts PATH, health officials

Bill and Melinda Gates Foundation-funded agency bypassed ethics and rules while conducting clinical trials for vaccine which was administered to girls, says panel

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A Parliamentary Committee report has indicted government officials and a US agency for colluding to conduct unethical clinical trials for HPV vaccine against cervical cancer in Andhra Pradesh and Gujarat. The set rules and procedures were overlooked by Indian government agencies while allowing clinical trials among adolescent girls for Human Papilloma Virus (HPV) vaccine. It is also clear that the American agency wanted to enter immunisation programmes globally to ensure fixed market for its products without investment in promotional marketing, and played with rules to attain the objective expeditiously.

The Parliamentary Standing Committee on Health and Family Welfare submitted its 72nd report—Alleged Irregularities in the Conduct of Studies Using Human Papilloma Virus (HPV) Vaccine by PATH in India to both houses of Parliament on August 30. In 2010, Khammam district in Andhra Pradesh reported death of children and adolescent girls after they were administered HPV vaccines. The Bill and Melinda Gates Foundation-funded Programme for Appropriate Technology in Health (PATH) was conducting the vaccination trials. The parliamentary committee has been investigating the matter since April 2010 following allegations by public health groups of irregularities in conducting the trials. The HPV vaccines tried were of companies GlaxoSmithKline and Merck.

The trials were conducted directly on girls before they were tried on adults, a major violation of rules in India. PATH described the project as observational study rather than clinical trial. The committee noted this was an attempt to avoid lengthy and strict procedures and enter the vaccination market at the earliest. The committee goes on to say that no matter what the nomenclature of a trial is, it has to follow some basic standards, which PATH did not follow.

The committee also wondered about clearance given by the Central Drugs Standard Control Organization. It asked if the authority even checked the design before

ICMR official's role questioned

The Committee found that the Indian Council of Medical Research signed a memorandum of understanding to provide technical support to the project in 2006 even before the Drugs Controller General of India (DGCI) approved its use in the country, which actually happened in 2008. The report has also brought out the differences between opinions of DCGI and ICMR, implicating a particular official of ICMR for clearly favouring the project.

“The report has come down heavily on government agencies and PATH, which is good. It shows that the violations happened from both sides,” said Sarojini N of Sama: Resource Group for Women and Health. The organisation has been highlighting violation in these trials since 2010.

“The Committee feels that there was serious dereliction of duty by many of the institutions and individuals involved. The Committee observes that ICMR representatives, instead of ensuring highest levels of ethical standards in research studies, apparently acted at the behest of the PATH in promoting the interests of manufacturers of the HPV Vaccine,” says the report.

The committee has also taken the exception to the fact that ICMR entered in public-private partnership (PPP) with PATH because such involvement gives rise to conflict of interest. It recommended the government to look into role of ICMR functionaries in the matter.

Matter of global attention

The committee has asked the Indian government to open dialogue at global level about the findings of the committee. The trials are being conducted in three more countries, namely Uganda, Vietnam and Peru. The committee has recommended the government to take up the matter with these countries through diplomatic channels to take action accordingly. It has also urged the government "to report the violations indulged in by PATH to international bodies like WHO and UNICEF so as to ensure that appropriate remedial action is initiated by these agencies worldwide."

The committee observed that the choice of countries for study, unlimited market potential for universal immunisation programmes and monopolistic nature of the product point towards well-planned scheme to commercially exploit a situation. "Had PATH been successful in getting the HPV vaccine included in the universal immunisation programme of the concerned countries, this would have generated windfall profit for the manufacturer(s) by way of automatic sale, year after year,

1981: PATH registered as Public Benefit Corporation (PBC) in the United States

1999: PATH gets a PAN card from Income Tax Dept. Shows it as proof of establishing office in India. No evidence of permission from MEA or MHA, which is mandatory for a foreign company to come to India

2006: PATH and ICMR sign MoU

2008: CDSCO approves marketing of drugs in India

2008: PATH claimed it received huge donation from health ministry. The health minister denied the same in Rajya Sabha.

2010: Reports of deaths of children and adolescent girls in Khammam, Andhra Pradesh

2010: Formation of three-member Enquiry Committee; report submitted same year

2011: DCGI proposes "additional" steps as action taken in response to Enquiry Committee report. The steps, in fact, have nothing new or additional to offer

Human Papilloma Virus (HPV) vaccine

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Sama Resource Group for Women and Health Sarojini N

Programme for Appropriate Technology in Health (PATH)

Parliamentary Standing Committee report on HPV vaccine

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